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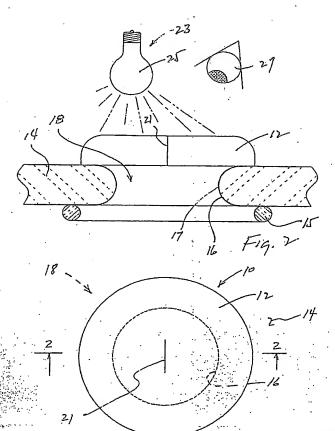
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- (71) Applicant (for all designated States except US): AP-PLIED MEDICAL RESOURCES CORPORATION [US/US]; 22782 Avenida Empressa, Rancho Santa Margarita, CA 92688 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): DULAK, Gary, R.

[US/US]; 6 Mojo Court, Newport Beach, CA 92663 (US). HILAL, Nabil [US/US]; 25291 Spindlewood, Laguna Niguel, CA 92677 (US).

- (74) Agent: MYERS, Richard; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).
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(54) Title: APPARATUS AND METHOD FOR ILLUMINATING A PERITONEAL CAVITY DURING LAPAROSCOPIC SURGERY



(57) Abstract: A surgical valve is adapted to access a body cavity through an incision in the body wall. valve is preferably formed of a gel material which defines a slit through the valve, the slit having properties for forming an instrument seal in the presence of an instrument and a zero seal in the absence of an instrument. The gel material preferably has transparent characteristics facilitating illumination and observation of the body cavity through the valve. Preferred omni-directional light is produced by multiple light sources which can be embedded in the gel of the valve.

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APPARATUS AND METHOD FOR ILLUMINATING A PERITUREAL CAVITY DURING LAPAROSCOPIC SURGERY BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to apparatus and methods associated with

laparoscopic surgery, and more specifically to illumination devices adapted for
use in hand-assisted laparoscopic surgery.

Discussion of Related Art

particular than the same

In laparoscopic surgery there is need for a sealing device which can seal around the surgeon's hand while permitting use of the hand in the pressurized peritoneal space. In the past, laparoscopic surgery has been viewed through a laparoscopic camera which supplies its own illumination. It is not uncommon for this illumination to be less than desirable, but there have been few options available to the surgeon to increase the illumination of the surgical field.

Laparoscopic illumination of the past has also been accomplished solely with point-source lighting. This has tended to create shadows which have made it even more difficult to perceive the three dimensional environment.

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SUMMARY OF THE INVENTION

In accordance with the present invention, a hand-assisted laparoscopic device is provided with transparent characteristics facilitating the transmission of light into and out of the abdominal cavity. As disclosed and claimed in Applicant's co-pending application, Serial No. 60/449,857, filed on February 25, 2003 and entitled Hand-Assisted Laparoscopy Apparatus and Method, this laparoscopic device may take the form of a pad which is placed over an incision extending through the abdominal wall. The pad can be formed of a gel material and provided with a slit to facilitate access for the surgeon's hand and other instruments into the abdominal cavity.

In accordance with the present invention, the gel forming the laparoscopic pad can be provided with translucent characteristics and preferably transparent characteristics. An external light can then be shown through the pad to illuminate the surgical environment. The transparent characteristics also operate to facilitate the surgeon's visualization of the operative site through the transparent device.

The illumination is preferably provided by a plurality of lamps in order to avoid shadows. The lamps can be carried by the transparent device and spaced around the slit. Preferably the lamps will be at least partially disposed within the transparent gel.

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In one aspect, the invention includes a surgical valve adapted for use in a surgical procedure to access a body cavity through an incision in a body wall.

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The valve has a generally open state facilitating formation of a first seal in the presence of an instrument extending through the incision and into the body cavity. The valve has a generally closed state facilitating formation of a second seal in the absence of the instrument extending through the incision and into the body cavity. A valve body is formed of a seal material and provided with a size sufficient to cover the incision. Perimeter seal means is carried by the seal material and adapted to form a perimeter seal with the body wall around the incision. Portions of the valve body define a slit and operate to form the first seal and the second seal. The slit extends through the valve body within the perimeter seal. A source of light is carried by one of the valve body and the perimeter seal means for lighting the body cavity through the incision to facilitate visualization of the surgical environment.

In another aspect, the invention includes a source of light which is disposed relative to the valve body and produces an omni-directional light for illuminating the surgical environment. The omni-directional light tends to eliminate shadows in the body cavity. These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

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DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a top plan view of a sealing device adapted for use in handassisted laparoscopy, the device being formed of a translucent material facilitating the transmission of light to and from the surgical site;
 - FIG. 2 is an axial cross section view taken along lines 2-2 of FIG. 1;
- FIG. 3 is a top plan view similar to FIG. 1 and illustrating multiple illumination lamps embedded in the device and spaced around the perimeter of the device; and
- FIG. 4 is an axial cross section view taken along lines 4-4 of FIG. 3.

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DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

The hand-assisted laparoscopic device is disclosed and claimed by Applicant in United States Patent Application Serial No. 60/449,857 filed on February 25, 2003, and entitled Hand-Assisted Laparoscopy Apparatus and Method. This application, which is fully incorporated herein by reference, discloses a hand-assisted laparoscopic device 10 in the form of a pad 12. The pad 12 is adapted for placement on a body wall, such as the abdominal wall 14, and forms a seal with the wall 14 around an incision 16 which extends through the wall 14 and into a body cavity, such as the abdominal cavity 18. A slit 21 extending through the pad 12 communicates through the incision 16 with the

abdominal cavity 18. In operation, the pad 12 is placed on the abdominal wall 14 over the incision 16. With this disposition, a primary seal is formed between the abdominal wall 14 and the perimeter of the pad 12. This seal is intended to maintain the inflation or pneumoperitoneum of the abdominal cavity 18 during laparoscopy surgery. This primary seal can be facilitated by a wound retractor including an internal anchor or ring 15 and an elastomeric sheath 17.

Various laparoscopic devices, including the surgeon's hand, can be inserted through the slit 21 to perform surgical procedures within the abdominal cavity 18. In the presence of these instruments, including the surgeon's hand, a secondary seal must be formed around the instrument by the material defining the slit 21.

In a preferred embodiment, this material includes a gel with elastomeric and compliant characteristics sufficient to form the secondary seal around the instrument, such as the surgeon's wrist.

In accordance with the present invention, the gel material forming the device 10 is provided with translucent characteristics to facilitate the transmission of light to and from the abdominal cavity 18. In a preferred embodiment, the translucent material is effectively transparent.

As illustrated in Figure 2, the transparent characteristics of the pad 12 facilitate the illumination of the abdominal cavity 18, for example, with an exterior light source 23. Even a unidirectional light source, such as a lamp 25 can be used in this manner as its light will be somewhat diffused by the pad 12 to provide for omni-directional illumination of the abdominal cavity 18. Of course

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the transparent characteristics of the device 10 also facilitate the transmission of light outwardly from the abdominal cavity 18 to permit visualization represented schematically in Figure 2 by an observer's eye 27.

The hand-assisted laparoscopic device 10 provides a large base which can be used to support several of the lamps 25 or other devices to illuminate the peritoneum cavity, as illustrated in Figure 3. This illumination can be in the form of fiberoptic lighting, illumination lamps or even LED's which can be carried by the device 10 and in some cases built directly into the device 10. The lamps 25 are preferably positioned around the perimeter of the device in order to supply even illumination to the operating field. With multiple sources of illumination, troublesome shadows can be minimized.

As illustrated in the embodiment of Figure 3, the multiple illumination lamps 25 can be embedded in the gel of the pad 12 in order to provide omnidirectional illumination within the abdominal cavity 18. Not only does this provide for total illumination of the abdominal cavity, but it does so without producing the three-dimensional shadows of the past. As noted, the lamps 25 can be carried by the gel of the device 10, partially embedded in the gel of the device 10, or even fully embedded in the gel of the device 10. In the latter case, the transparency of the gel is of particular importance.

It can be seen from the foregoing discussion that laparoscopic illumination can be facilitated with intrinsic illumination devices, providing an omni-directional light within the abdominal cavity 18. Even extrinsic illumination can be accommodated with a transparent hand-assist device which facilitates

illumination of the abdominal cavity and direct visualization of the operative site.

In either case, the illumination devices can be carried by the hand-assist device,
or partially or totally embedded within the device.

Notwithstanding the foregoing description, it will be understood that many other modifications can be made to the various disclosed embodiments and method steps, without departing from the spirit and scope of the concept. For example, various sizes of the surgical device are contemplated as well as various types of constructions and materials. It will also be apparent that many modifications can be made to the configuration of parts as well as their interaction. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of preferred embodiments. Those skilled in the art will envision other modifications within the spirit and scope of the present invention as defined by the following claims.

CLAIMS

1. A surgical valve adapted for use in a surgical procedure to access a body cavity through an incision in a body wall, the valve having a generally open state facilitating formation of a first seal in the presence of an instrument extending through the incision and into the body cavity, and a generally closed state facilitating formation of a second seal in the absence of the instrument extending through the incision and in to the body cavity, the valve comprising:

valve body formed of a seal material, the valve body being of a

valve body formed of a seal material, the valve body being of a size sufficient to cover the incision;

perimeter seal means carried by the seal material and forming a perimeter seal with the body wall and around the incision;

portions of the valve body defining a slit extending through the valve body within the perimeter seal, the portions being adapted to form the first seal in the presence of the instrument and the second seal in the absence of the instrument; and

a source of light carried by one of the valve body and the perimeter seal means for lighting the body cavity through the incision to facilitate visualization of the body cavity.

2. The surgical valve recited in Claim 1, wherein the source of light is a source of omni-directional light.

- 3. The surgical valve recited in Claim 2, wherein the seal material is a gel.
 - 4. The surgical valve recited in Claim 3, wherein the gel is translucent.
- 5. The surgical valve recited in Claim 3, wherein the source of omnidirection al light is carried by the gel.
- 6. The surgical valve recited in Claim 5, wherein the source of omnidirectional light is embedded in the gel.
- 7. The surgical valve recited in Claim 2, wherein the source of omnidirectional light comprises a plurality of individual lamps.
- 8. A surgical valve adapted for use in a surgical procedure to access a body cavity through an incision in a body wall, the valve having a generally open state facilitating formation of a first seal in the presence of an instrument extending through the incision and into the body cavity, and a generally closed state facilitating formation of a second seal in the absence of the instrument extending through the incision and in to the body cavity, the valve comprising:

a valve body formed of a seal material, the valve body being of a size sufficient to cover the incision;

perimeter seal means carried by the seal material for forming a perimeter seal with the body wall and around the incision;

a source of light disposed relative to the valve body and producing an omni-directional light path, the path extending through the incision to illuminate the body cavity.

- 9. The surgical valve recited in Claim 8, wherein the source of light is carried by the valve body.
- 10. The surgical valve recited in Claim 9, wherein the light path extends through at least a portion of the valve body.
- 11. The surgical valve recited in Claim 8, wherein the source of light includes a plurality of unidirectional light sources.
- 12. The surgical valve recited in Claim 8, wherein the seal material is a translucent gel.
- 13. A surgical valve adapted for use in a surgical procedure to access a body cavity through an incision in a body wall, the valve having a generally open state facilitating formation of a first seal in the presence of an instrument extending through the incision and into the body cavity, and a generally closed

- state facilitating formation of a second seal in the absence of the instrument extending through the incision and in to the body cavity, the valve comprising:
 - a valve body formed of a seal material, the valve body being of a size sufficient to cover the incision;
- portions of the valve body defining a slit extending through the valve body and communicating with the incision in the body wall; and
 - the valve body being formed of a generally translucent material providing for the passage of light through the valve body to facilitate visualization of the body cavity through the incision.
 - 14. The surgical valve recited in Claim13, wherein the valve body is formed of a generally transparent material providing for the passage of light through the valve body to facilitate illumination of the body cavity through the incision.
 - 15. The method for illuminating a surgical site in a body cavity defined by a body wall, comprising the steps of:

providing a surgical valve adapted to facilitate instrument access through the body wall and into the body cavity; and

illuminating the body cavity with an omni-directional light.

16. The method recited in Claim 15, wherein:

the providing step includes the step of producing the valve from a

5 "transparent material; and

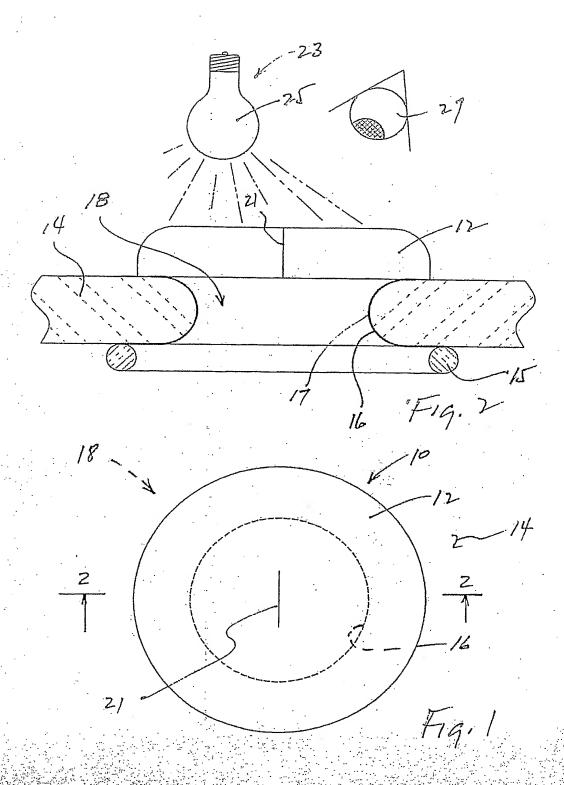
the illuminating step includes the step of illuminating the body cavity through at least a portion of the translucent material of the surgical valve.

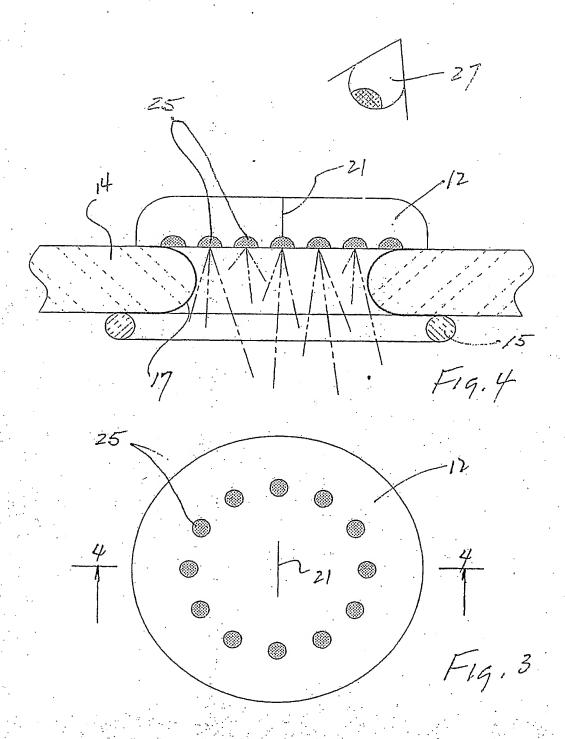
17. The method recited in Claim16, wherein the illuminating step further comprises the steps of:

providing a source of omni-directional light; and carrying the source of omni-directional light with the surgical valve.

18. The method recited in Claim 17, wherein the carrying step includes the step of:

imbedding at least a portion of the source of omni-directional light in the translucent material of the surgical valve.





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- (72) Inventors; and
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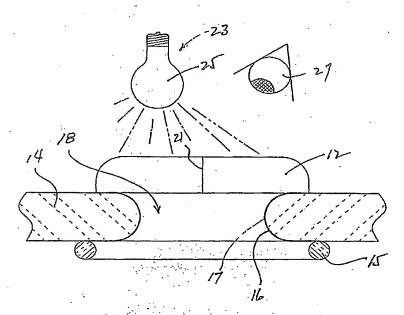
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(54) Title: APPARATUS AND METHOD FOR ILLUMINATING A PERITONEAL CAVITY DURING LAPAROSCOPIC SURGERY



(57) Abstract: A surgical valve (12) is adapted to access a body cavity (18) through an incision (16) in the body wall (14). The valve (12) is preferably formed of a gel material which defines a slit (21) through the valve (12), the slit (21) having properties for forming an instrument seal in the presence of an instrument and a zero seal in the absence of an instrument. The gel material preferably has transparent characteristics facilitating illumination and observation of the body cavity (18) through valve (12). Preferred omnidirectional light is produced by multiple light sources (25) which can be embedded in the gel of the valve (12).

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INTERNATIONAL SEARCH REPORT

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| A. CLASSIFICATION OF SUBJECT MATTER | |
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| IPC(7) : A61B 1/32 | |
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| Category * Citation of document, with indication, where appropriate, of the relevant passages Y U.S. 5.814 026 A (YOON) 29 September 1008 (20 00 1008) 75 and 10 10 10 10 10 10 10 10 10 10 10 10 10 | Relevant to claim No. |
| 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - | 1-18 |
| lines 35-46, column 7, lines 1-67 and column 8, lines 43-51. Y US 5.865.779 A (MEEHAN et al) 03 February 1800 (23 1000) Figure 2 0 0 5 | |
| Y US 5,865,729 A (MEEHAN et al) 02 February 1999 (02.02.1999), Figures 2, 3, 5A through 5D, column 4, lines 26-49 and column 6, lines 31-62. | 1-18 |
| Y US 5,353,786 A (WILK) 11 October 1994 (11.10.1994), Figures 1-4, 18 and 22, column | |
| lines 12-24, column 4, lines 38-68, column 5, lines 1-57 and column 8, lines 34-42 | i |
| X,P WO 03/032819 A1 (EWERS) 24 April 2003 (24.04.2003), Figures 2-5, 43 and 44 and p | page 1-18 |
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